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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/511,445	02/22/2000	William J. Gordon-Kamm	1115	1983

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Pioneer Hi-Bred International Inc
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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 07/15/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/511,445

Applicant(s)

GORDON-KAMM ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on CPA filed 05/02/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,5,6 and 9-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,5,6 and 9-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16. 6) ☐ Other: _____

DETAILED ACTION

Continued Prosecution Application

The request filed on May 2, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/511445 is acceptable and a CPA has been established. An action on the CPA follows.

The Preliminary Amendment filed May 2, 2002, paper no.15, has been entered.

Claims 1, 4 and 7 are cancelled.

Claims 3, 5, 9, 10 and 12 are newly amended.

Claims 13-17 are newly added.

Claims 3, 5-6 and 9-17 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed May 2, 2002, Paper No. 16, is attached to the instant Office action.

Claim Objections

Claims 3, 5, 9, 10 and 12 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 3, 5, 9, 10 and 12 depend from subsequent claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 10-14 and 15-17 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to methods for increasing endoreduplication and crop yield by stably transforming a plant with an isolated plant geminivirus replicase polynucleotide.

The specification describes only one plant geminivirus replicase polynucleotide that increases endoreduplication and yield when expressed in a transgenic plant, a polynucleotide encoding a wheat dwarf virus RepA protein. This does not constitute a substantial portion of the genus of plant geminivirus replicase polynucleotides which encode a protein that increases endoreduplication and crop yield when expressed in a transgenic plant. Timmermans et al. teach that geminiviruses constitute a large group of viruses that differ with respect to genomic organization, host range, and insect vector (1994, Ann. Rev. Plant Physiol. Plant Mol. Biol., Vol. 45, pages 79-112, Applicant's IDS, see pages 81-89). With respect to geminivirus replicases in particular, replicases from different subgroups of geminiviruses have structural differences that may be indicative of functional differences (Xie et al., 1995, The EMBO Journal, Vol. 14, No. 16, pages 4073-4082, Applicant's IDS, see page 4076 column 1 first full paragraph - page 4077 first column first paragraph and Figure 4; Collin et al., 1996, Virology, Vol. 219, pages 324-329,

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Applicant's IDS, see page 328; Gutierrez, 1998, Current Opinion in Plant Biology, Vol. 1, pages 492-497, Applicant's IDS, see page 494). The claimed genus encompasses numerous diverse plant geminivirus replicase polynucleotide sequences, including those yet to be discovered, yet the specification does not describe any plant geminivirus replicase polynucleotide other than a polynucleotide encoding a wheat dwarf virus RepA protein that increases endoreduplication and yield when expressed in a transgenic plant. The disclosure of only one geminivirus replicase polynucleotide that increases endoreduplication and yield when expressed in a transgenic plant does not provide an adequate description of the claimed genus. One skilled in the art would not recognize from the disclosure that at the time of filing the applicant was in possession of the genus that comprises plant geminivirus replicase polynucleotides which encode a protein that increases endoreduplication and crop yield when expressed in a transgenic plant.

Claims 3, 5-6 and 9-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for increasing endoreduplication and crop yield by stably transforming a plant with an isolated wheat dwarf virus RepA geminivirus replicase polynucleotide, does not reasonably provide enablement for methods for increasing endoreduplication and crop yield by stably transforming a plant with an isolated plant geminivirus replicase polynucleotide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to methods for increasing endoreduplication and crop yield by stably transforming a plant with an isolated plant geminivirus replicase polynucleotide.

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The specification teaches that introduction of an isolated viral replicase polynucleotide derived from the vector pWI-11 into maize scutellar cells causes increased reduplication in nuclei isolated from the leaves of transgenic plants as compared to nuclei isolated from the leaves of wild-type plants (pages 21-24 *Examples 1 and 2*), and that expression of the isolated viral replicase polynucleotide could be regulated by the use of tissue specific, cell specific, or inducible promoters (page 24 *Example 3*). Additionally, the previously submitted declaration under 35 C.F.R. 1.132 by William J. Gordon-Kamm discloses that transgenic maize and soybean plants transformed with a polynucleotide encoding the wheat dwarf virus Rep A protein exhibit increased endoreduplication and increased plant size. The specification does not teach whether an increase in endoreduplication and plant size would be brought about by the introduction of any other isolated geminivirus replicase polynucleotide, such as by transforming plants with polynucleotides encoding replicases from geminiviruses other than wheat dwarf virus.

Guidance for making and using the claimed invention is necessary for enablement because the ability of a plant geminivirus polynucleotide to increase endoreduplication and yield when expressed in a transgenic plant is highly unpredictable. Xie et al., Collin et al. and Gutierrez teach that while geminivirus replicases share structural and functional similarities, geminivirus replicases from different subgroups of geminiviruses also have structural differences that may be indicative of functional differences (1995, *The EMBO Journal*, Vol. 14, No. 16, pages 4073-4082, Applicant's IDS; 1996, *Virology*, Vol. 219, pages 324-329, Applicant's IDS; 1998, *Current Opinion in Plant Biology*, Vol. 1, pages 492-497, Applicant's IDS) In particular, Xie et al., Collin et al. and Gutierrez teach that most replicases from subgroup I geminiviruses, such as wheat dwarf virus, have an LxCxE motif, whereas replicases from subgroup II and III

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geminiviruses lack an LxCxE motif (Xie et al. see page 4076 column 1 first full paragraph - page 4077 first column first paragraph and Figure 4; Collin et al. see page 328; Gutierrez see page 494). Such a difference could be functionally significant in that proteins having an LxCxE motif have been implicated in the binding and inactivation of retinoblastoma proteins, and such inactivation causes cells to transition from the G1 to the S phase of the cell cycle (Grafi et al., August 1996, Proc. Natl. Acad. Sci. USA, Vol. 93, pages 8962-8967, Applicant's IDS). Given that endoreduplication requires transition from the G1 to the S phase of the cell cycle, it is possible that such a difference could be also be functionally significant with respect to the claimed methods. Furthermore, Hanley-Bowdoin et al. teach transformation of tobacco plants with an isolated tomato golden mosaic virus geminivirus replicase polynucleotide operably linked to a CaMV35S promoter capable of driving expression in a plant cell (February 1990, Proc. Natl. Acad. Sci. USA, Vol. 87, pages 1446-1450, Applicant's IDS). In contrast to the increased plant size and endoreduplication observed by Applicant in transgenic plants expressing the wheat dwarf virus geminivirus replicase, Hanley-Bowdoin et al. report that transgenic tobacco plants expressing the tomato golden mosaic virus geminivirus replicase are phenotypically normal (see page 1450 column 1 last paragraph). Thus, while one skilled in the art could readily transform a plant with any known plant geminivirus replicase polynucleotide, the specification does not provide sufficient guidance for one skilled in the art to recognize which plant geminivirus replicase polynucleotide would be likely to increase endoreduplication and yield when expressed in a transgenic plant. In the absence of such guidance, it would require undue experimentation for one of skill in the art to practice the claimed invention, even though

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plant geminivirus replicase polynucleotides were known in the art at the time of Applicant's invention.

Given the uncertainty of whether any plant geminivirus replicase polynucleotide will increase endoreduplication and yield when expressed in a transgenic plant, the absence of guidance in the specification for selecting a plant geminivirus replicase polynucleotide, the lack of working examples, and given the breadth of the claims which encompass methods for increasing endoreduplication and crop yield as a result of introducing into a plant any plant geminivirus replicase polynucleotide, it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

The rejection of claims 7 and 9-12 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "growing the transformed plant cell under conditions sufficient to produce a regenerated plant having cells exhibiting increased endoreduplication" is withdrawn in light of the cancellation of claim 7.

Claim Rejections - 35 USC § 102

The rejection of claims 1 and 3-6 rejected under 35 U.S.C. 102(e) as being anticipated by Gronenborn (US 6,133,505 October 17, 2000) is withdrawn in light of the cancellation of claims 1 and 4 and the amendment of claims 3 and 5.

Remarks

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210.

The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
July 12, 2002

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800

